

**RESEARCH SERVICE**

**April 1, 2008**

**RESEARCH STANDARD OPERATING PROCEDURES**

**Training for Research Involving Human Subjects**

**1. PURPOSE:** All individuals involved in human research must receive the training necessary to ensure human research is carried out in an ethical and safe manner. The purpose of this policy is to identify individuals for whom human research education is required, the training that will satisfy this requirement, and the procedures for confirming that individuals have met the training requirements.

**2. POLICY:** Individuals involved in human research studies will be required to receive appropriate training in the ethical principles and accepted practices for the conduct of human subjects' research. This training meets the VA and Federal requirements for human research training.

**3. ACTION:**

- a. Individuals Involved: The following individuals are required to complete the designated training in the protection of human research subjects and Good Clinical Practice (GCP) :
  - (1) All investigators and their research staff involved in research studies involving human subjects.
  - (2) Members of the Research Office, exclusive of secretarial support
  - (3) Members of the R&D Committee
- b. Course:
  - (1) The VA has made available an on-line course that effectively communicates the ethical principles and acceptable practices for human subject's research. Completion of this course satisfies the VA human research training requirement. Current instructions can be found on the South Texas Veterans Health Care System's Research Office webpage at: <http://www.south-texas.med.va.gov/research/html/training.htm> for taking the CITI Course in the Protection of Human Research. Research staff may be contacted at 210-617-5300 x15523 for further assistance.
- c. Frequency: All individuals must complete this training annually.
- d. Documentation: Upon completion of the course, the Research Office is sent an automatically generated email from CITI with a link to the individuals' certificate of completion.

**POLICY MEMORANDUM 151-08-20**

- e. Tracking: The Research Office will print and maintain a copy of all training certificates. A database of current training dates will be maintained to track training compliance. Current training status will be verified at the time of protocol submission and at the time of continuing review.
  - (1) New Protocol Submission: The principal investigator is required to submit a list of all investigators and research staff participating in the project and documentation of their training. The Research Office will check the training database and documentation to insure all personnel listed have completed the required training. Final R&D Committee approval will not be given until training has been confirmed for all individuals listed on the project.
  - (2) Continuing Review: At the time of continuing review, the Research Office will verify that training is current (within twelve months) for all personnel listed, and will contact the Principal Investigator if any personnel lack current training. Only personnel who have current training will be allowed to participate in the activities related to the protocol. Continued Approval will not be given and approval of the protocol will expire, if the Principal Investigator does not provide documentation of current training.
  - (3) Non-project personnel: The Research Office will maintain a record of the dates of training for Research Office staff and R&D Committee members. The Administrative Officer or his designee will, at least quarterly, review the training data to initiate reminders to staff and R&D Committee members when training will be due and follow up to insure updated training is completed.
- f. Other Federal requirements: OHRP requires that responsible institutional officials complete specific OHRP on-line training modules prior to issuing a Federal-Wide Assurance. This requirement must be met prior to any FWA submissions. The Research Office will provide the dates of training on the FWA application at the time of any resubmissions.

- 4. **REFERENCES:** Office of Research and Development, VACO, memo dated March 6, 2003.
- 5. **RESPONSIBILITY:** ACOS for Research and Development (151)
- 6. **RESCISSION:** Research Service Policy Memorandum 04-20, dated May 28, 2004.
- 7. **RECERTIFICATION:** March 2011.

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ACOS for Research and Development